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71 Applicant: MEDTRONIC, INC.
 3055 Old Highway Eight
 Minneapolis Minnesota 55440(US)

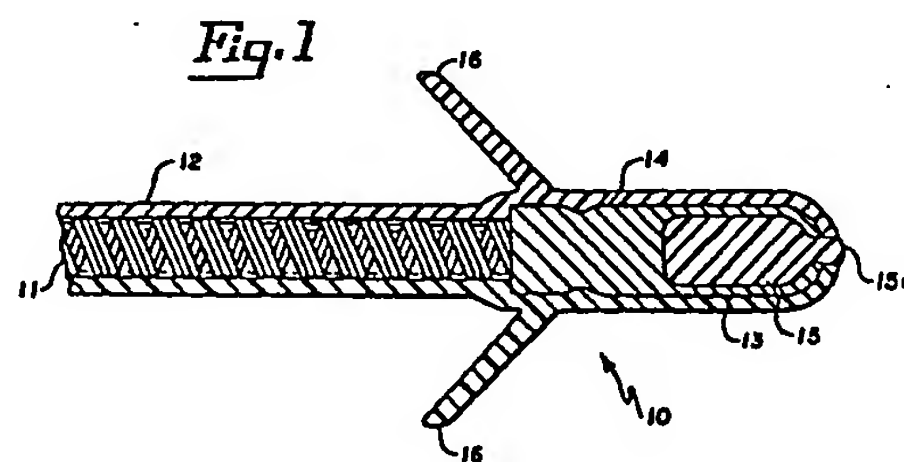
72 Inventor: Juncker, David F.
 16 E Minnehaha Parkway
 Minneapolis, Minn. 55427(US)

72 Inventor: Williams, Terrell M.
 1444 97th Avenue N.W.
 Coon Rapids, Minn. 55433(US)

74 Representative: Schwan, Gerhard, Dipl.-Ing.
 Elfenstrasse 32
 D-8000 München 83(DE)

54 Implantable medical lead.

57 Body implantable lead (10) having a polymer-based gel
 DCD (Differential Current Density) electrode (15)



BODY IMPLANTABLE LEAD
WITH IMPROVED DCD ELECTRODE

I. DESCRIPTION

Background of Prior Art

5 Electrical stimulation of the body for medical purposes is well known in the prior art. An example of a device for this purpose is the cardiac pacemaker. In the pacemaker context, as well as other body stimulation contexts, the stimulation is delivered to the desired body
10 site by an electrode component of a lead.

 A variety of body implantable electrical leads for the delivery of electrical stimulation energy to a desired body site are also known in the prior art. Recent years have seen increased usage of transvenous leads which can
15 deliver the stimulation energy to the desired body site while significantly lowering patient risk and morbidity. For example, the use of a transvenous/endocardial lead eliminates the necessity of a thoracotomy while delivering stimulation energy to the heart to provide a pacemaking
20 function.

 In many stimulation contexts, maintenance of a reliable electrical contact at the desired electrode site has proven difficult. Interactions between the lead and the contact site can vitiate the desired effects of the stimulation. For example, material reactions may encourage
25 fibrosis. In the pacemaking context, fibrosis is believed to be a major factor in the increase in chronic threshold that is usually experienced. Also, mechanical trauma may result in inflammation of the tissue to be stimulated. Such inflammation may alter the response of the tissue to
30 the stimulation energy, both acutely and chronically.

 In the chronic use of such leads, it has been observed that the contractions of the heart against the lead and the mechanical pressure applied against the heart by the
35 lead may traumatize the contacted tissue. The traumatized tissue may form scar tissue around the electrode(s). In chronic experience, it is observed that the threshold currents sufficient to stimulate the heart increase as the

scar tissue is formed until the thickness of the scar tissue stabilizes. The required energy to stimulate the heart is thereby increased because of the additional potential drop across the nonresponsive cardiac cells. A discussion of this mechanism in conjunction with the realization of optimum electrode surface area appears in the paper entitled "Comparison of Power Sources for Advanced Pacemaker Applications" by Rasor, Spickler and Clabaugh, Proceedings of the Seventh Intersociety Energy Conversion Engineering Conference, January 1972, pages 752-760.

Pressure induced trauma are believed to be the leading cause of enlarged fibrotic encapsulation of implanted electrode tips.

In addition, cardiac tissue is occluded under the tip and deprived of access to oxygen and water soluble nutrients carried by the blood while also being deprived of the ability to transfer waste products from the tissue into the blood. A large number of tissue cells are so occluded by existing endocardial electrode tips because cells of heart tissue must communicate with the blood in the ventricles of the heart by way of diffusion due to the lack of capillaries near the endocardial surface.

The interactions noted above have long been recognized and efforts have been made to ameliorate their consequences. For example, leads have been configured to reduce mechanical trauma and the response of irritable tissue during lead placement. Materials have been selected for the lead body and electrodes to minimize fibrosis. Thrombus formation may also be countered by the administration of suitable drugs.

The administration of drugs to counter the undesirable interactions between the lead and body noted above has not gained widespread acceptance in that it has heretofore required a systemic treatment to counter a localized interaction. Also, lead configuration must take into account other factors such as focus of sufficient current density into viable, depolarizable tissue, the efficiency of the delivery of the stimulation energy, the ease of lead place-

ment, maintenance of the desired electrode position and reliability of the lead over extended periods of time. An accommodation of these interests has resulted in leads whose configuration necessarily results in undesirable interactions between the lead and body.

Other interactions, such as electrochemical and polarization effects, between the electrode and body at the contact site, can result in the occurrence of undesirable events, and waste energy stored in pacemaker batteries.

In some circumstances where electrical stimulation of body tissue is indicated, the tissue to be stimulated is irritable. The placement of a pacemaking lead may induce a cardiac arrhythmia. The presence of the lead may also promote thrombus formation.

The behavior of the metals employed as stimulation electrodes in implantable leads has long been of considerable interest, particularly in such applications as cardiac pacemakers. In most commercial pacemaker leads, the electrodes are of platinum or a platinum alloy. The lead is inserted into the heart tissue or into the right ventricle by transvenous catheter. The energy required to stimulate the heart depends on the particular electrode used. For any given stimulation electrode, the electrical behavior of the tissue around it and the effect of the electrode on the tissue can be evaluated from the stimulation threshold and the operational value of the electrode circuit. The term "threshold" means the smallest amount of electrical energy which will produce consistent cardiac contraction with the electrode system used when the stimulation impulse is delivered after the absolute and the relative refractory period of the heart.

Typically, the threshold increases during the first weeks of implantation caused by interstitial edema and the growth of connecting tissue around the lead electrode tip. With metallic electrodes the stimulation energy cannot be substantially reduced by changing the surface area of the electrode or the impulse duration.

Since high current density and a small electrode is

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required locally to stimulate the cardiac muscle, polarization effects develop with the consequence that most of the delivered energy from the pacemaker circuit is wasted in the electrode electrolyte interface, a region which is termed the Helmholtz layer. Polarization losses are particularly important in the case of implanted pacemakers since their life time is determined by the amount of energy stored in their batteries. Considerable improvement of the system life time can be achieved if the stimulation system is used more economically.

It is recognized that ideally the processes taking place at electrode contact surfaces should be solely those involving motion of electric charges by ion carriers without polarization effects. Unfortunately, the requirement for high current density is ordinarily accompanied by high polarization effects. In implantable leads, polarization effects exist in the vicinity of the Helmholtz layer wherein the interchange from the electron flow of the metal electrode to the ionic flow of the electrolyte (body fluids) occurs.

Parsonnet et al described a non-polarizing electrode in "Clinical Use Of A New Transvenous Electrode", Ann. N.Y. Acad. Sci., 167:756, 1969. In this system, termed a "Differential Current Density Electrode" the waste of energy due to polarization effects was reduced by providing a low current density at the metal electrode to avoid polarization and a high current density at the point of contact to the endocardium. This system provided lowered stimulation thresholds but suffered from electrochemical instability during long-term operation.

Another type, a purely capacitive electrode, was described by Schaldock in an article entitled "New Pacemaker Electrodes", Transactions:American Society Artificial Internal Organs, Volume 29, pages 29-35, 1971.

Brief Summary of the Invention

Generally, this invention provides a non-metallic replacement electrode for the noble metal or other metal electrodes used heretofore in implantable leads. The

replacement electrode comprises a conductive polymer-based gel, preferably a hydrogel, which may be cast to shape or formed in situ. The polymer-based gel electrode, due to its configuration, avoids the polarization phenomena associated with metal electrodes in a conductive fluid as is encountered in living bodies. The electrode of the invention provides a transition zone where electron flow is converted to ionic flow i.e., the Helmholtz layer. With metal electrodes, the Helmholtz layer is external to the electrode and is such that cells in its vicinity are disrupted or otherwise damaged. With the polymer-based gel electrode of the invention a transitional synthetic layer is provided in the electrode where this reaction can take place.

Significant advantages of the improved implantable lead of the invention are: reduced tissue trauma; use of inexpensive gel electrode rather than expensive precious metal electrodes; improved electrode-tissue interface, mechanically, chemically and electrically; use of non-corroding electrode material, and protection of the living cells from any electron/ion conversion reaction.

Most significantly, however, this invention provides an improved DCD electrode for implantable leads wherein the polymer-based gel electrode body is provided with a relatively small surface area and high ion current density for tissue contact. The polymer-based gel body provides a volume in which the electric charge flow interchange occurs rather than in the body fluids (electrolyte) whereby polarization effects occur in the electrode proper and not in the fluids at the tissue contact area. By providing a relatively large surface area of polymer gel body for contacting the lead means and providing electron flow to the gel electrode body i.e., large relative to the stimulating surface area of the gel electrode, it is possible to provide for high interchange of electron to ion flow with relatively low impedance while providing high current density at the relatively small stimulating, tissue contact surface of the gel electrode.

This objective is achieved by providing large area contact between the conductive lead means/gel body and relatively small, tissue contact surface area at the stimulating surface of the gel electrode. Small surface area
5 at stimulating portion of the gel electrode may be controlled by aperture size in the lead body and by gel body size at the exposed contact portion of the gel body and by various combinations of these two aspects.

Specifically then, the present invention provides im-
10 plantable leads having conductive polymer-based gel electrodes of a predetermined configuration which ameliorate the effects of undesirable interactions between the lead and the contacted tissue. This is accomplished by providing, as the electrode, a body of soft, compliant, water
15 swellable, polymeric, water insoluble material non-toxic to body tissues and fluids. The material preferably consists essentially of a hydrogel which is ionically conductive. The hydrogel is permeable to water, oxygen, CO₂ and the like. Consequently, their diffusion may occur through
20 the cushioning body both to and away from the occluded tissue cells at the contact site. The water permeable hydrogel body is ionically conductive thereby providing electrical contact between the metal electrode and the tissue.

25 Brief Description of the Drawings

Figure 1 illustrates a portion of a body implantable lead having a polymer gel electrode in accordance with a preferred embodiment of the present invention.

Figure 2 is an end view of the body implantable lead
30 shown in Figure 1.

Figures 3 and 4 are fragmentary showings of the distal end of implantable leads having differing polymer gel electrode configurations according to the invention.

Detailed Description of the Invention

35 The concept of using a conductive polymer gel as the stimulating and sensing medium in an implantable trans-

venous lead, particularly in a cardiac pacing lead, arose from considerations of the electrochemistry at the electrode/tissue (electrolyte) interface. The charge carriers in metal and similar electrical conductors are electrons
5 whereas charge is carried by ions in electrolyte solutions. When metal is immersed in an electrolyte, charge flows from one phase to another until the electrochemical potentials of the metal and electrolyte phases are equal. This results in the build-up of a layer of charge, called the
10 Helmholtz layer, around the surface of the electrode. This phenomenon is termed polarization and results in a dissipative energy loss that shortens pulse generator battery life. Electrochemical reactions may also result in corrosion of the electrode metal, depending on the
15 metal used.

In addition to the detrimental effects of the Helmholtz layer on device operation, there is some question as to whether the chronic presence of a charge layer near the tissue causes myocardial and endocardial pathologic processes. For example, the Helmholtz layer may chronically
20 alter the local pH in the vicinity of the electrode. The chronic imbalance of charge may affect the membrane properties such that changes in myocardial and endocardial cell depolarization threshold occur.

25 Because of the known, as well as the unknown or speculative, effects attributable to the Helmholtz layer, the gel electrode of the invention is proposed as a solution for, among other things, minimizing these adverse consequences of polarization. Because the metal electrolyte interface in the gel electrode design is removed from
30 the vicinity of the tissue, the Helmholtz layer is believed to be encapsulated in the gel. Since charge transport is by ionic movement in the gel, the ions can diffuse into and out of the gel freely and a charge layer is not established at the surface of the gel at which tissue contact
35 is established. A large metal surface contacting the gel decreases the impedance of the Helmholtz layer. Also, the ion concentration can be increased by increasing avail-

able charge carriers, as in the case of 2-acrylamido-2-methylpropanesulfonic acid and salt polymers thereby reducing polarization and impedance even further. Improved sensing and lower stimulation thresholds result
5 from the combined effects of repositioning of the Helmholtz layer and minimizing charge imbalances in the vicinity of the myocardial cells.

Referring now to Figures 1 and 2, there is illustrated a DCD body implantable lead constructed in accordance with
10 the present invention. The lead body, designated 10, is comprised of an insulating plastic such as polyurethane and is attached to a coiled, flexible conductor 11 and an overlying sheath 12. Coiled, flexible conductor 11 may be of any known design and preferably has a central aperture
15 which will accept a stylet (not shown) to provide stiffness during lead placement, in known manner. The lead body may also be non-linear such that stylet insertion will straighten the lead body to facilitate transvenous placement, also in known manner. To facilitate flexibility requirements as well as for reliability considerations,
20 flexible conductor 11 may be a multi-filar member. Conductor 11 is in electrical communication with a polymer gel electrode 15 by means of a metal crimp-sleeve 14 and a conductive electrode receptacle 13 providing a large
25 area of contact to polymer gel body 15 interior of lead body 10. Lead body 10 is sealed around electrode 15 so as to prevent the entrance of body fluids and the like. For example, it may be partially encapsulated in urethane polymer, mechanically interlocked or otherwise adhered thereto.
30 A source of stimulation energy (not shown) for the delivery of stimulation energy to a desired body site is connected to conductor 11. Sheath 12 may be a preformed tubular member, preferably of a body compatible polyurethane the same as lead body 10, to overlie conductor 11
35 and provide electrical insulation therefor, in known manner. Also, as is known, lead body 10 may be tined as indicated at 16.

In the prior art, many lead bodies are formed of a molded silicone. A preferable material for sheath 12 and lead body 10 is a body-compatible polyurethane. Such polyurethanes meet the flexibility requirements of trans-
5 venous leads and are typically less thrombogenic than silicone and more resistant to tearing and cutting. In general, the physical characteristics of polyurethane are more suited to transvenous leads than those of silicone, although silicone or any other body compatible material may be employed in practicing the present invention.
10

Polymer-based gel electrode 15 may be provided in various configurations. It may be pre-cast or polymerized in situ, as desired.

In the embodiment shown, conductive metal receptacle
15 13 which may be of platinum, platinum-iridium, stainless steel, titanium or the like defines a cavity which contains polymer electrode 15 with a rounded end portion 15a thereof extending through the open distal end of the lead body. The end portion may also be flat. The rounded or
20 flat end provides an exposed portion for establishing electrical contact between living tissue and the lead. It also provides a small surface area for tissue contact relative to its interior surface area and volume of contact with conductive receptacle 13. Such a configuration
25 provides a low energy density at the interior contact surface and a high energy density at the tissue contact surface. A flat end portion will help focus the current through non-viable tissue to provide higher current density at the depolarizable myocardial level.

30 Figures 3 and 4 illustrate other gel electrode configurations which provide a first portion inside body 10 having large area electrical contact with the electron source interiorally relative to the exposed second portion which provides a small area tissue contact.

35 A wide variety of lead configurations, including bipolar as well as unipolar, and polymer gel body configurations consistent with the tissue contacting requirements of the lead may be utilized.

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Electrode body 15 may consist of any conductive polymer gel. However, it preferably consists essentially of a hydrogel thick enough to allow space for the Helmholtz layer. Typically, thicknesses i.e., the dimension of body 15 extending out of the lead body, will range from about 0.5 mm to about 1.0 mm. Such an electrode body has been found to provide low mechanical trauma and high electrochemical interface with endocardial tissue.

Hydrogels of the invention are ionically conductive, soft, compliant, water swellable and inert to body tissues and fluids. Body 15 is also ionically conductive and permeable thereby establishing electrical communication between lead means 11 and the contacted tissue as well as providing a diffusion path to and away from the occluded tissue site.

Generally speaking, a hydrogel having the properties above described will comprise a coherent, three-dimensional polymeric network capable of imbibing water without dissolving. Usually, insolubility in water is provided by incorporating a crosslinked structure in the polymer. Hydrogels or water-containing gels may be comprised of water and various chemical substances including gelatin; polysaccharides; crosslinked acrylamide polymers; hydroxyethylmethacrylate polymers crosslinked polyhydroxyethylacrylate; polymerized, crosslinked 2-acrylamido-2-methylpropane sulfonic acid or one of its salts such as the sodium or potassium type; crosslinked polyvinylpyrrolidone; polyacrylic acid; copolymers of the aforementioned monomers with each other, and copolymers of the aforementioned monomers with other monomers such as styrene or other non-hydrogel forming monomers.

Hydrogels of low conductivity may be made conductive for purposes of this invention by incorporating salts such as sodium chloride, potassium chloride and like electrolytic salts into the hydrogel. This is most easily accomplished by dissolving a salt in a monomer-water-initiator solution and polymerizing. Other methods of preparation may also be used.

The specific preferred hydrogels are crosslinked polyacrylamide and crosslinked polymerized 2-acrylamido-2-methylpropane sulfonic acid or one of its salts. Volume 15, pages 273-291 of the Encyclopedia of Polymer Science
5 Technology (1971), John Wiley Publishers, provides a section entitled HYDROGELS which describes the preparation of a variety of water-imbibing polymers. The content thereof is incorporated herein by reference.

EXAMPLE - Polyacrylamide Hydrogel

10 The following ingredients were dissolved in 52.5 grams of deionized water: 40.0 grams acrylamide, 2.0 grams sodium chloride, 8.0 cc of a 1% aqueous solution of methylene-bis-acrylamide. Nitrogen was vigorously bubbled through the resultant solution for 2.5 minutes. The fol-
15 lowing reagents were added to the solution simultaneously with stirring: 0.5 cc of a .38% solution of potassium bisulfite, 0.5 cc of a .38% solution of potassium persulfate, and 0.5 cc of a .24% solution of ferrous sulfate.

A portion of the resultant mixture was withdrawn into
20 a syringe and ejected into the cavity of electrode tip 13 under a nitrogen atmosphere. The mixture was cured to form the hydrogel by allowing it to stand under the nitrogen atmosphere until solidified.

It is to be understood that, within the scope of the
25 appended claims, the invention may be practiced otherwise than as specifically described.

WHAT IS CLAIMED IS:

II. CLAIMS

1. An implantable lead comprising a conductive polymeric electrode body having a large electrical contact portion and a relatively small tissue contact portion;
5 electrical contact means comprising a body of metal contacting the electrical contact portion of the electrode; lead body means carrying the electrode and enclosing the electrical contact means and the electrical contact portion of the electrode against exposure to tissue and body
10 fluids, and electrical conductor means connected to the electrical contact means.

2. In a body implantable lead of the type having electrode means, elongated electrical conducting means and lead body means extending between the electrode means and
15 the elongated electrical conducting means, the improvement wherein the electrode means comprises a conductive polymer-containing body defining an electrical contact portion and a tissue contacting portion, the electrical contact portion being larger than the tissue contacting portion, and
20 the lead body means defines an insulating and sealing electrode enclosure for holding and enclosing the electrical contact portion of the electrode body against exposure of that portion of the electrode to body tissue and body fluids, the lead body means carrying the tissue contacting portion of the electrode in an exposed position
25 thereon and including conductor means connected to the elongated electrical conducting means and to the electrical contact portion of the electrode body, the connection at the electrode portion being of relatively large area and
30 comprising substantially all of the surface of the contact portion of the electrode body.

3. A body implantable lead of the transvenous type including: means for supplying electrical energy to the lead; a lead body; a conductive polymeric-based electrode
35 body carried by the lead body for providing electrical contact between the electrical supply means and living

tissue, the electrode body having an electrical contact surface and a tissue contact surface, the tissue contact surface being small relative to the electrical contact surface, and large area contact means connected between
5 the electrical supply means and substantially the entire electrical contact surface of the electrode body for supplying electrical energy thereto.

4. A body implantable lead of the transvenous type including a lead body, the exterior of the lead body being
10 comprised of insulating material; a body of conductive polymer-based gel carried by the lead body with a first portion enclosed thereby and a second exposed portion for providing electrical contact between the body implantable lead and living tissue, the surface area of the second
15 portion being smaller than that of the first portion, and electrical lead means extending through the lead body and interiorally connected to the polymer-based gel body over substantially the entire surface area of the first portion.

5. A body implantable lead of the transvenous type
20 including a lead body having a distal end, the exterior of the body being comprised of insulating material; a body of conductive polymer-based gel carried at the distal end of the lead body with a first portion enclosed thereby and a second portion exposed by the body for providing electrical
25 contact between the body implantable lead and living tissue, the surface area of the second portion being smaller than that of the first portion, and electrical lead means extending through the lead body and interiorally connected to the polymer gel body over substantially the entire
30 surface area of the first portion.

6. A body implantable lead of the transvenous type including a lead body having a distal end, the exterior of the lead body being comprised of insulating material, the body defining a cavity having an opening at the distal end
35 thereof; a body of conductive polymer-based gel contained

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in the cavity with a relatively small portion thereof exposed through the cavity opening for providing a contact surface for contacting living tissue, electrical contact means in the cavity and extending over substantially the entire enclosed surface of the polymer-based gel body, and electrical lead means extending through the lead body and interiorally connected to the electrical contact means.

7. The lead of any of the preceding claims 1, 2, 3, 4, 5 or 6 wherein the tissue contacting portion of the polymer body defines a rounded configuration.

8. The lead of any of the preceding claims 1, 2, 3, 4, 5 or 6 wherein the tissue contacting portion of the hydrogel body defines a flat configuration.

9. The lead of any of the preceding claims 1, 2, 3, 4, 5 or 6 wherein the polymeric gel consists essentially of a hydrogel.

10. The lead of claim 9 wherein the hydrogel includes a crosslinked polymer.

11. The lead of claim 9 wherein the hydrogel includes a copolymer.

12. The lead of claim 9 wherein the hydrogel includes an acrylamide.

13. The body implantable lead of claim 12 wherein the acrylamide polymer is crosslinked.

14. The body implantable lead of claim 9 wherein the hydrogel includes a hydroxyethylmethacrylate polymer.

15. The body implantable lead of claim 9 wherein the hydrogel includes a crosslinked ethylacrylate polymer.

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16. The body implantable lead of claim 9 wherein the hydrogel includes a crosslinked polymer of 2-acrylamido-2-methylpropane sulfonic acid or one of its salts.

17. The body implantable lead of claim 16 wherein
5 the hydrogel includes a copolymer.

18. The body implantable lead of claim 9 wherein the hydrogel includes a crosslinked vinylpyrrolidone polymer.

19. The body implantable lead of claim 9 wherein the hydrogel includes a copolymer.

10 20. The body implantable lead of claim 19 wherein the copolymer is comprised of at least two copolymerized hydrogel-forming monomers.

21. The body implantable lead of claim 19 wherein the copolymer is comprised of at least one hydrogel-forming
15 monomer and one non-hydrogel-forming monomer copolymerized together.

22. The body implantable lead of any of the preceding claims 1, 2, 3, 4, 5 or 6 wherein the polymer-based gel contains relatively large ionic concentration relative
20 to the tissue to be contacted.

Fig. 1

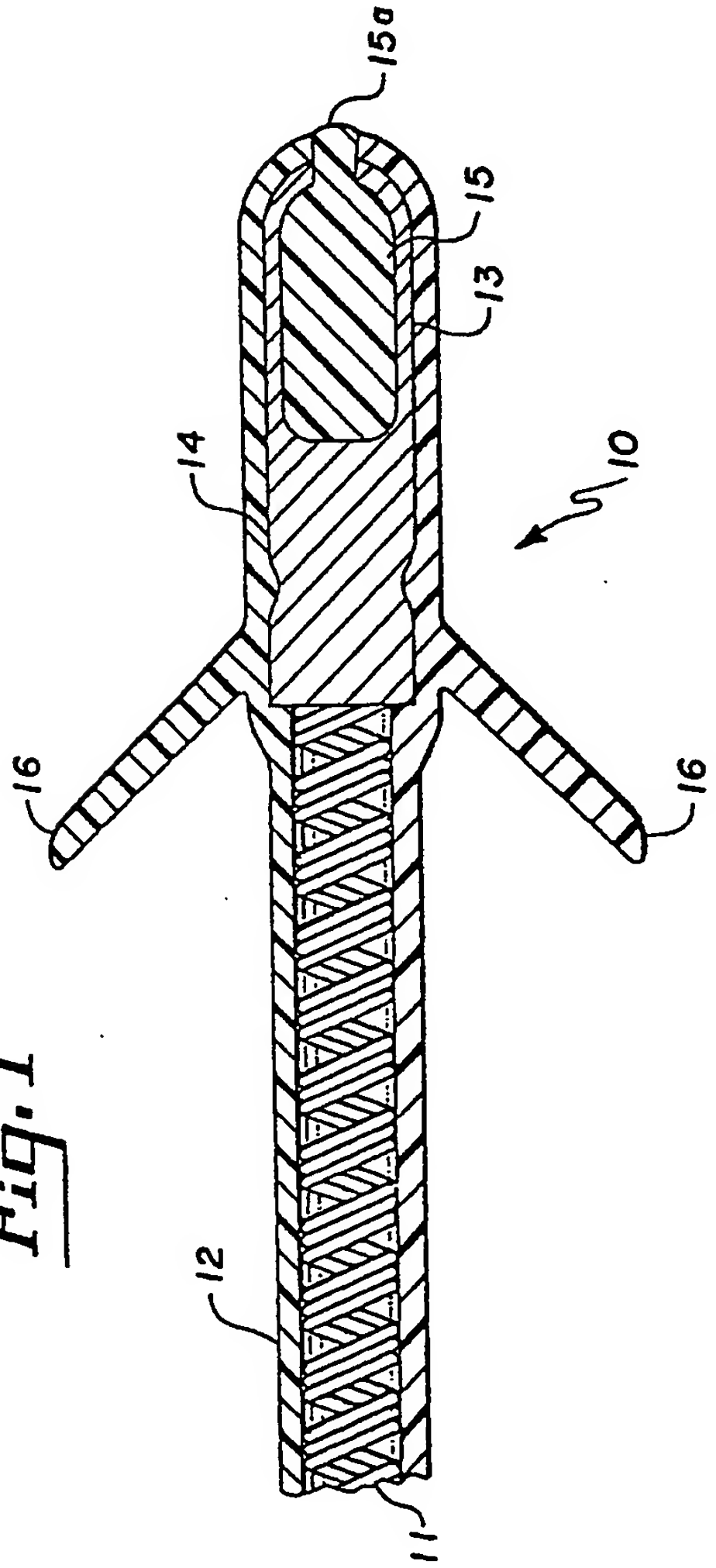


Fig. 2

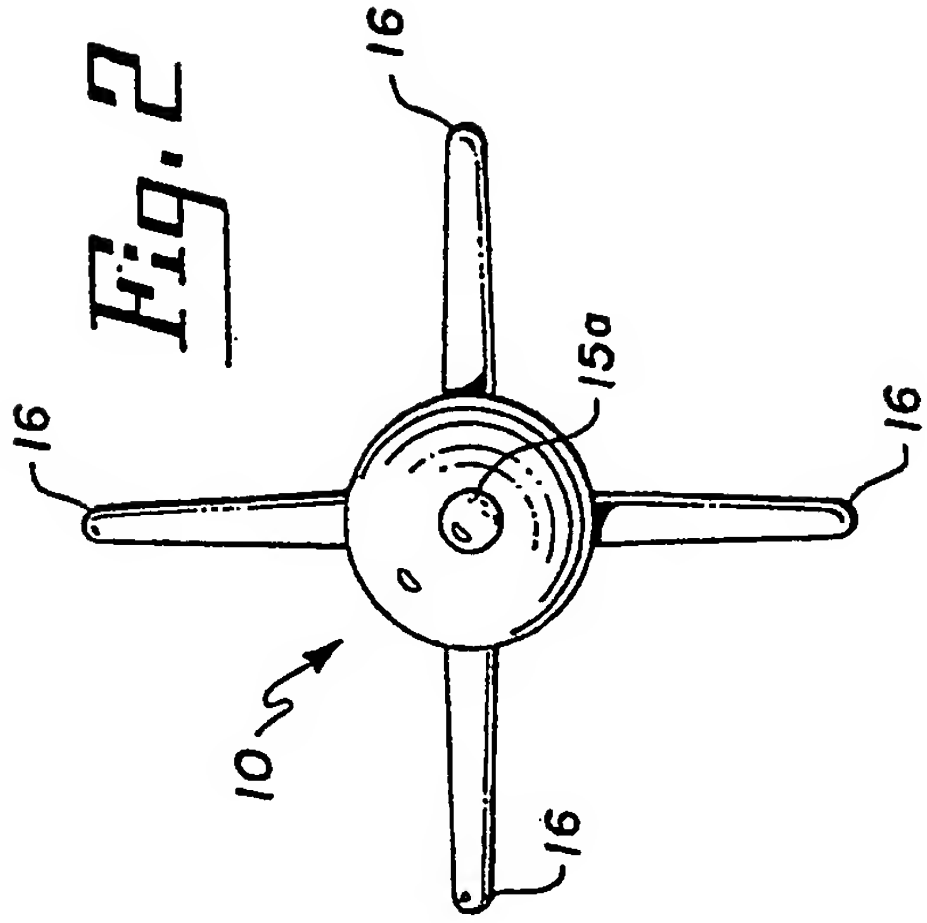


Fig. 3

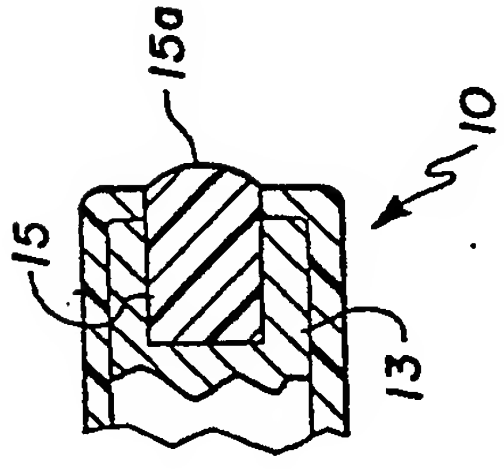
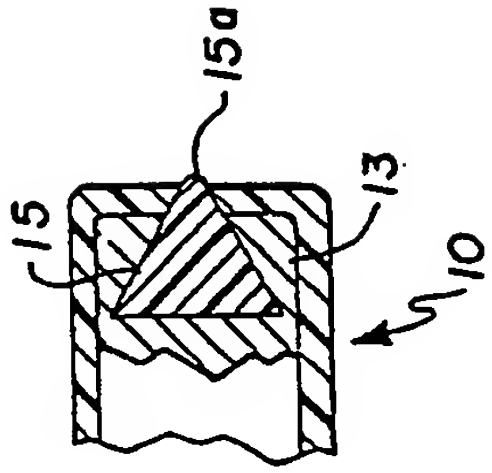


Fig. 4





European Patent
Office

EUROPEAN SEARCH REPORT

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Application number

EP 82 10 0642

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl. ³)
A	DE-A-3 006 472 (BECK) *Page 8, line 16 - page 9, line 16, page 14, line 15 - page 15, line 20; figures 1-3*	1,2,7	A 61 N 1/04
A	--- US-A-3 476 116 (PARSONNET) *Column 3, lines 28-59; figures 3-5*	1,3,4,6,8	
A	--- US-A-4 230 604 (WINGRAVE) *Column 2, lines 1-65* -----	10-22	
			TECHNICAL FIELDS SEARCHED (Int. Cl. ³)
			A 61 N A 61 B H 01 B
The present search report has been drawn up for all claims			
Place of search THE HAGUE		Date of completion of the search 29-04-1982	Examiner BIJN E.A.
CATEGORY OF CITED DOCUMENTS			
X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document		T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document	